



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 14, 2008

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 84368-R
DP Barcode 348872

From: Wallace Powell, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

A handwritten signature in blue ink, likely belonging to Wallace Powell.

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

A handwritten signature in blue ink, likely belonging to Karen Hicks.

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward, PM 34/ Lisa McKelvin
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Mandala Technologies LLC

ACTIVE INGREDIENT
Ethanol

% by wt.
29.4

BACKGROUND

The applicant has submitted an eye irritation study (MRID 473202-04) in order to complete the product-specific acute toxicity data support for registration of the subject product DETOX™, EPA File Symbol 84368-R. The other such support was reviewed in Product Science Branch memorandum of dated 9/11/2007, Data Package 340584.

RECOMMENDATION

The submitted eye irritation study is acceptable.

Recommended acute toxicity profile:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	Waiver request	IV	Waived
Acute Dermal Toxicity	Waiver request	IV	Waived
Acute Inhalation Toxicity	Waiver request	IV	Waived
Primary Eye Irritation	473202-04	II	Acceptable
Primary Skin Irritation	Waiver request	III	Waived
Dermal Sensitization	Waiver request	Non-sensitizer	Waived

Product labeling:

The proposed human-hazard precautionary labeling in the label draft (dated January 2008) is acceptable except that it omits the instruction to "avoid contact with skin" as indicated in the Agency's Label Review Manual (August 2007, Chapter 7, available at www.epa.gov/oppead1/labeling/lrm).

The proposed First Aid statements are acceptable. However, if the First Aid section is not going to be placed on the front panel, a referral should be placed on the front panel. As stated in the Label Review Manual:

First Aid statements for toxicity categories II and III classification may appear on any panel of the label. However, any time First Aid statements appear other than on the front panel, a referral statement such as, "See side/back panel for First Aid" should appear on the front panel in close proximity to the Signal Word.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (OPPTS 870.2400)

Product Manager: 34
MRID No.: 473202-04

Reviewer: W. Powell
Study Completion Date: 10/22/2007
Report No.: 23035

Testing Laboratory: Eurofins | Product Safety Laboratories – Dayton, New Jersey
Author: Carolyn Lowe

Quality Assurance (40 CFR §160): Quality Assurance statement and Good Laboratory Practice statement were included.

Test Material: DETOX, Lot #090707-1, a clear liquid

Dosage: 0.1 mL

Species: Rabbit, New Zealand albino

Sex: 3 Females

Age: Young adult

Weight: Not indicated

Source: Robinson Services, Inc. – Clemmons, NC

Housing: Temperature Range: 19-22°C

Relative Humidity: 60-82% (The study report states that the "humidity reading of 82% was due to a temporary malfunction of the environmental control system.")

Photoperiod: 12-hour light/dark cycle

Acclimation: 19 days

Summary:

1. **Toxicity Category:** II
2. **Classification:** Acceptable

Procedure/Reporting Deviations from Guideline 870.2400: None noted

Results:

The test substance caused corneal opacity in all 3 animals, persisting to Day 7 in 2 of 3 animals; and iridal involvement in all 3 animals, persisting to Day 7 in 1 of 3 animals. "Positive" degree of conjunctival redness persisted to Day 4 in 2 of 3 animals. "Positive" degree of conjunctival swelling persisted to 72 Hours in 3 of 3 animals. Conjunctival redness and swelling reached no higher than grade 2 on the Draize scale. Conjunctival discharge was advanced (grade 3 on the Draize scale) in 3 of 3 animals at 48 hours. No other adverse ocular effects were observed. All notable effects cleared by Day 10.

Based on these results, DETOX appears moderately irritating and is placed in eye irritation Toxicity Category II.

Incidence of Irritation

Time Post-Instillation	No. of Animals Testing "Positive" / No. of Animals Tested			
	Corneal Opacity	Iritis	Conjunctival Redness	Conjunctival Chemosis
1 hour	3 / 3	3 / 3	3 / 3	3 / 3
24 hours	3 / 3	3 / 3	3 / 3	3 / 3
48 hours	3 / 3	3 / 3	3 / 3	3 / 3
72 hours	3 / 3	3 / 3	3 / 3	3 / 3
Day 4	2 / 3	2 / 3	2 / 3	0 / 3
Day 7	2 / 3	1 / 3	0 / 3	0 / 3
Day 10	0 / 3	0 / 3	0 / 3	0 / 3